

UNIVERSITY OF TORONTO

Office of the Vice-President, Research and Associate Provost

Ethics Review Office

PROTOCOL REFERENCE #20362

August 20, 2007,

Dr. Frances Silverman Gage Occupational and Environmental Health Unit 223 College St. Toronto, ON M5T 1R4 Dr. Marie Faughnan St. Michael's Hospital 30 Bond St. Toronto, ON M5B 1W8 **Deleted:** June 13, 2007 **Deleted:** June 13, 2007

Dear Dr. Silverman and Dr. Faughnan:

Re: Your research protocol entitled "Cardiovascular Toxicity of Concentrated Ambient Fine, Ultrafine and Coarse Particles in Controlled Human Exposures"

A member of the Health Sciences II Research Ethics Board has considered this study under the REB's expedited review process. As a result of the review you are asked to respond to the following points:

- Is the amount of financial compensation adequate for this considerable amount of time required?
- Nitrolingual tablets frequently cause marked head aches in de novo people. What provisions
 are there for people experiencing major headaches?
- What provisions are there for people where abnormalities are discovered on testing eg ECG,
 Echo etc. This needs to be stated in the consent form.

Please address individual review points in a cover letter and attach the revised materials to your response. Additions/revisions to the original protocol and supporting documents should be highlighted.

If your revisions are **more than fifteen pages**, please submit two copies to the Ethics Review Office in Simcoe Hall. If your revisions are **fifteen pages or less** you have the option to submit one copy by email (ethics.review@utoronto.ca) or fax (416-946-5763).

Yours sincerely,

Jenny Peto Ethics Review Coordinator

Simcoe Hall, Room 10A, 27 King's College Circle, Toronto Ontario M5S 1A1 TEL: 416/ 946-3273 FAX: 416/ 946-5763 EMAIL: ethics.review@utoronto.ca